

## The Patentability of Surgical Methods at the EPO

Article 53(c) EPC excludes methods for the treatment of the human or animal body by therapy or surgery from patentability at the EPO. The meaning of "treatment by surgery" was discussed in an Enlarged Board of Appeal case, G1/07. In this case, the Board was asked whether a physical intervention practised on the human or animal body, which is carried out as part of an imaging method, causes that method to be excluded from patent protection as encompassing a method of treatment by surgery, even if the physical intervention step was not carried out per se at maintaining life and health. In answering this question, some useful guidance was provided as to the patentability of surgical methods at the EPO.

The referral was from an application containing claims to magnetic resonance imaging in which an imaging agent was delivered to the subject. The claims encompassed both inhalation of the agent and its injection into the heart. The Enlarged Board considered that such an injection represented a substantial physical intervention on the body which entails a health risk and requires professional medical expertise to be carried out, and that as such it could be regarded as a method for the treatment of the human or animal body by surgery and hence excluded from patentability. This is the case, irrespective of the fact that the physical intervention on the body is not itself aimed at maintaining life and health.

Previously, the Technical Boards of Appeal at the EPO had provided conflicting decisions as to the meaning of "treatment by surgery". Some earlier cases had stated that it is the nature of the physical intervention that is important, i.e. that the term "treatment by surgery" might comprise treatments which were not directed to restoring or maintaining health. Others had considered the purpose of the physical intervention to be more important, and had stated that to fall within the exclusion the method had to be at least potentially suitable for maintaining or restoring the health, physical integrity or physical well-being of a human being or an animal.

In G1/07, the Board decided that it is the nature of the step that is determinative. They considered that an approach based on the purpose of the physical intervention might give rise to opposing judgements in relation to a single physical intervention (injection of a medicament being excluded, but injection of a cosmetic substance for reducing wrinkles not being excluded). Other approaches, such as whether a medical or veterinary practitioner should be responsible for carrying out the method steps, were dismissed as not providing sufficient legal certainty. As such, the exclusion of "treatment by surgery" cannot be seen as limited to surgery which is performed for a therapeutic purpose. For example, the exclusion also applies to cosmetic surgery.

The Board indicated that a method of treatment by surgery is one which relates to a substantial physical intervention on the body which entails a health risk even when carried out with the required medical professional care and expertise, and requires professional medical expertise to be carried out. They did not set out exact boundaries of what should be meant by "treatment by surgery", but left this open for Examiners and the Boards of Appeal to determine on a case by case basis, based on the technical facts of each case. It was acknowledged that there is no general concept for acts regarded as surgical in the medical sense, and the scope of what is surgery may change with time and with new technical developments.



The exclusion from patentability of methods of treatment by surgery is based on public health interests. The Board indicated, however, that it does not appear to be justified to exclude all physical interventions from patentability in the interests of public health. Advances in safety and the fact that many new, safe and routine, albeit invasive, techniques are performed in non-medical, commercial environments mean that such safe and routine methods (at least when performed on uncritical parts of the body) may not fall within the exclusion. In this respect, a comment in a previous Enlarged Board of Appeal Decision (G1/04) that "any physical intervention" is an excluded method of surgery was stated to be overly broad.

The Enlarged Board of Appeal also confirmed that a method is excluded from patentability under Article 53(c) EPC as being a method for treatment by therapy or surgery if it comprises or encompasses at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy. Multi-step methods comprising or encompassing a single surgical step are thus excluded from patentability. It is of note that the exclusion applies even if the step is not explicitly claimed.

Claims cannot encompass such a surgical step and the wording of claims in this field must be chosen carefully in order for the claim to meet all the requirements of the EPC, including the fact that all the essential features needed to define the invention should be recited. Again, this should be determined on a case by case basis.

Although this Decision confirms that any method comprising a step of surgical intervention is excluded from patentability, this is balanced by a less strict definition of what is meant by surgical intervention than has previously been set out by the EPO. It is clear that some methods that would previously have been excluded from patentability may now be considered patentable, particularly those in which the invasive step is safe and routine, and one which is commonly carried out in commercial settings.

### Further advice

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